DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 8, 2014

Advanced Technology Laser Company, Ltd
% Ms. Diana Hong
Mid-Link Consulting Company, Ltd
P.O. Box 120-119
Shanghai, 200120 CHINA

Re: K140249
Trade/Device Name: Long Pulse Nd:YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 5, 2014
Received: September 8, 2014

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
2014.10.08 12:44:48 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140249

Device Name

Long Pulse Nd:YAG Laser System

Indications for Use *(Describe)*

Long pulse Nd:YAG Laser System is intended for use for :

• Benign pigmented lesions such as ,but not limited to , lemtigos(age spots), solar lentigos(sun spots), café au lait macules, seborrheic karatoses, nevi, chloasma, verrucae, skin tags, karatoses, tattoss(significant reduction in the intensity of black and/or blue black tattoos) and plaques.
• Pigmented lesions to reduce lesion size, for patients with lesions that would potientlly benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
• Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 3 510(k) Summary

This 510(k) Summary of 510(k) information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K140249

1. Date of Submission: 09/10/2014

2. Sponsor Identification

Advanced Technology Laser Co., Ltd.
920 Jian-chuan Road, Bldg. A2, Level 5,Shanghai, 200240, China

Establishment Registration Number: 3007604279;

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3. Submission Correspondent

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4. Proposed Device Identification

Trade Name: Long Pulse Nd:YAG Laser System;
Common Name: Nd:YAG Dermatology Laser System;
Model: SmoothTouch;

Regulatory Information:
Classification Name: Powered Laser Surgical Instrument;
Classification: II;
Product Code: GEX;
Regulation Number: 21CFR 878.4810;
Review Panel: Laser Instrument, Surgical, Powered;

Intended Use Statement:

Long pulse Nd:YAG Laser System is intended for use for :

- Benign pigmented lesions such as ,but not limited to , lemtigos(age spots), solar lentigos(sun spots), café au lait macules, seborrheic karatoses, nevi, chloasma, verrucae, skin tags, karatoses, tattoss(significant reduction in the intensity of black and/or blue black tattoos) and plaques.
- Pigmented lesions to reduce lesion size, for patients with lesions that would potientlly benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

5. Predicate Device Identification

510(k) Number: K022923
Product Name: Gentle YAG Laser System
Manufacturer: Candela Corporation

6. Device Description

The Long Pulse Nd:YAG Laser System is a flashlamp-excited, Nd:YAG (Neodymium-doped Yttrium Aluminum Garnet) laser system. Pulsed laser energy at a nominal wavelength of 1064nm. This wavelength causes maximum energy absorption by targeting the treatment area and minimum absorption by surrounding skin structures. In addition, the laser pulse duration is controlled to be equal to or shorter than the thermal relaxation time of the target, to minimize heat transfer to surrounding tissues.

Deeper penetration and a more moderate hemoglobin absorption makes 1064 nm wavelength more useful for the deeper hair follicles and vessels. Further, with the right combination of parameters, the 1064 nm wavelength is also suitable for more superficial hair, telangiectasia and spider veins.

Base on this, Long Pulse Nd:YAG Laser System is intended for 1) Benign pigmented lesions such as ,but not limited to , lemtigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic karatoses, nevi, chloasma, verrucae, skin tags, karatoses, tattoss (significant reduction in the intensity of black and/or blue black tattoos) and plaques. 2) Pigmented lesions to reduce lesion size, for patients with lesions that would potientlly benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. 3) Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

The Nd:YAG Laser System consists of control system, user interface, power source , laser emission and delivery system, cooling system and safety features

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General requirements for safety.

IEC60601-1-2:2007, Medical Electrical Equipment - Part 1: General requirements for safety - 2, Collateral Standard: Electromagnetic compatibility – Requirements and tests.

IEC 60601-2-22:2007, Medical Electrical Equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.

IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification, requirements

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device K022923
Product Code	GEX	GEX
Regulation Number	21CFR 878.4810	21CFR 878.4810
Intended Use	Long pulse Nd:YAG Laser System is intended for use for : Benign pigmented lesions such as ,but not limited to , lemtigos(age spots), solar lentigos(sun spots), café au lait macules, seborrheic karatoses, nevi, chloasma, verrucae, skin tags, karatoses, tattoss(significant reduction in the intensity of black and/or blue black tattoos) and plaques. Pigmented lesions to reduce lesion size, for patients with lesions that would potientlly benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.	SAME
Energy Source	ND:YAG Laser	SAME
Waveform	1064 nm	SAME
Fluence energy range	up to 600J/cm^2	SAME
Spot size	1.5mm, 3mm, 8mm, 10mm, 12mm and 3mm*8mm	SIMILAR
Aiming laser	510nm diode laser (<5mW), Class III	SIMILAR
Beam Delivery	Permanently attached umbilical cable and handpieces	SAME

The proposed device, Long Pulse Nd:YAG Laser System, is determined to be Substantially Equivalent (SE) to the predicate device, Gentle YAG Laser System, in respect of safety and effectiveness.